

REMARKS

Reconsideration of the rejections set forth in the office action dated June 16, 2004, is respectfully requested. Applicants have canceled claims 2-4, 7, and 8 without prejudice, and have added new claims 9 and 10.

Rejection of Claims 1-5 Under 35 U.S.C. Section 102(e)

The Examiner rejected claims 1-5 under 35 U.S.C. Section 102(e) for allegedly being anticipated by Alferness et al. (US 6293951). Applicants have canceled claims 2-4 without prejudice, and respectfully traverse this rejection with respect to claims 1 and 5.

Relevant Law

Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. All limitations in the claims must be found in the reference, since the claims measure the invention. Moreover, it is incumbent on the Examiner to identify wherein each and every facet of the claimed invention is disclosed in the reference.

Claim 1

Instant claim 1 is directed to a method for lung volume reduction comprising:

deploying an obstructive device in a lung passageway to a
lung tissue segment; and
aspirating the segment through the deployed obstructive
device to at least partially collapse the lung segment.

Argument

Claim 1 calls for deploying an obstructive device in a lung passageway. As described in the specification and drawings, e.g., page 6, lines 8-28 and Figures 1 and 2, the term "deploying an obstructive device in a lung passageway" means to guide an obstructive device into a lung passageway and to release the obstructive device in the lung passageway. Figure 2, for example, shows the obstructive device in its deployed state within a bronchiole. As shown in Figure 2, the obstructive device is released within the bronchiole such that it is not attached to a delivery catheter.

Alferness fails to show the steps of *deploying* an obstructive device in a lung passageway and then aspirating the segment through the deployed obstructive device to at least partially collapse the lung segment. Alferness describes the use of a catheter 70 having an inflatable member 74. The inflatable member 74 is threaded to a bronchial branch, inflated, and then removed without ever being deployed (i.e., released) in the bronchial branch. Unlike the method recited in claim 1 herein, the catheter 70 and inflatable member 74 are always connected to an extracorporeal apparatus and are never deployed in the manner of instant claim 1. Applicants, therefore, respectfully submit that claim 1 is patentably distinct from Alferness.

Claim 5

Claim 5 recites a system for obstructing a lung passageway to a lung tissue segment comprising:

an access catheter having a proximal end, a distal end, and
at least one lumen extending therethrough, and
an obstruction device deployable within the lung
passageway having an inlet port adapted for aspirating the lung
tissue segment through the port,
wherein the obstruction device is introduceable by the
access catheter.

Argument

Claim 5 calls for an obstruction device having an inlet port adapted for aspirating a lung tissue segment through the port. According to the Examiner, reference numeral 90 in Alferness shows an obstruction device having an inlet port adapted for aspirating the lung tissue segment through the inlet port. However, there is nothing in Alferness that describes the obstruction device 90 having an inlet port adapted for aspirating the lung tissue segment. The obstruction device 90 does not have such an inlet port because it is placed in the lung after the lung is collapsed by aspiration. At column 5, lines 11-29, Alferness describes collapsing the lung by pulling a vacuum through the catheter 70 such that a portion of the lung achieves a collapsed state. As shown in Figure 3 of Alferness, the obstruction device 90 is not present in the lung

while the vacuum is pulled. “With the lung portion 66 thus collapsed, and while the lung portion 66 is collapsed, an obstructing member 90 is guided through the main channel of the conduit 70 by a stylet wire 92.” (Alferness, column 5, lines 29-32 (emphasis added)). Thus, Alferness provides no teaching of the obstruction device 90 having an inlet port adapted for aspirating the lung, as the aspiration step in Alferness is performed prior to placement of the obstruction device. Consequently, Alferness fails to teach all of the limitations of claim 5 and the rejection under 35 U.S.C. 102(e) should be withdrawn.

Moreover, Alferness makes no mention whatsoever of aspirating the lung after the obstruction device is placed in the lung and, hence, there is no motivation or suggestion to modify the obstruction device 90 to have an inlet port adapted for aspirating the lung. Indeed, given that the device 90 has no anchoring member to retain the device in place in the presence of a vacuum, it is likely that the obstruction device 90 would be sucked out of the lung if an attempt was made to pull a vacuum therethrough. It would also be impossible to pass a suction catheter distally through the flaps of the obstruction device 90, as the flaps are retained by tethers that prohibit the flaps from opening in a distal direction.

Thus, Alferness fails to describe any situation where a vacuum would be pulled through the obstruction device. Alferness teaches only two ways to collapse a lung portion: (1) the lung is collapsed by aspirating, i.e. pulling a vacuum, in the lung before placement of the obstruction device (column 5, lines 11-33); or (2) not pulling a vacuum at all, but rather obstructing the diseased area and allowing the air within the obstructed lung portion to be absorbed by the body over time. (See col. 5, lines 54-64). Accordingly, there is no need or benefit in Alferness for an obstruction device with an inlet port adapted for aspiration through the device, because Alferness has solved the problem of collapsing a diseased lung portion by aspirating before placement of an obstruction device or by not aspirating at all. Consequently, Alferness not only fails to teach an obstruction device having an inlet port adapted for aspirating the lung through the port, but it actually teaches away from such a device. Applicants, therefore, respectfully submit that claim 5 is patentably distinct from Alferness.

Rejection of Claims 6-8 Under 35 U.S.C. Section 103

The Examiner rejected claims 6-8 under 35 U.S.C. Section 103 for allegedly being unpatentable over Alferness. in view of Daniel et al. (5980455). Applicants have canceled claims 7 and 8 without prejudice, and respectfully traverse this rejection with respect to claim 6.

Relevant Law

In order to establish a *prima facie* case of obviousness, there must be evidence, preferably a teaching, suggestion, incentive or inference from the cited art or in the form of generally available knowledge that one of ordinary skill would have been led to modify the relevant teaching to arrive at what is claimed. The prior art must provide a motivation whereby one of ordinary skill in the art would have been led to do that which the applicant has done. In addition, the mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification.

Claim 6

Claim 6 recites a kit comprising:

- an obstruction device *deployable* within a lung passageway; and
- instructions for use according to a method of lung volume reduction comprising:
 - deploying an obstructive device in a lung passageway to a lung tissue segment; and
 - aspirating the segment through the deployed obstructive device to at least partially collapse the lung segment.

Argument

Claim 6 calls for a kit that includes an obstruction device deployable within a lung passageway, and instructions for use that include deploying the obstructive device in a lung passageway and aspirating through the deployed device. As described above and in the specification and drawings, e.g., page 6, lines 8-28 and Figures 1 and 2, the term "deploying an

obstructive device in a lung” means to guide into position and to release an obstructive device in the lung. Figure 2, for example, shows the obstructive device in its deployed state within a bronchiole.

In contrast, Alferness describes the use of a catheter 70, which is threaded to a bronchial branch, inflated, and then removed without ever being released in the branch. Unlike the method recited in claim 1 herein, the catheter 70 is always connected to an extracorporeal apparatus and is never deployed. With respect to the “obstructive member 90” disclosed in Alferness, there is no teaching or suggestion of aspirating the lung tissue segment through that or any other obstructive member. Likewise, Daniel et al. fails to teach a method in which an obstructive device is deployed within a lung passageway, or aspirating a lung tissue segment through an obstructive device that is deployed within a lung passageway. Thus, even the combination of the two references cited by the Examiner does not suffice to provide all of the elements recited in claim 6. Applicants, therefore, respectfully submit that claim 6 is patentably distinct from the prior art references cited by the Examiner.

New Claims 9 and 10

Claims 9 and 10 have been added by way of this amendment. Neither claim adds new matter, and both are fully supported by the specification.

Claim 9 calls for a method that comprises releasing an obstructive device in a lung passageway. As explained above, neither Alferness nor Daniel teach such a method. Therefore, applicants respectfully submit that new claim 9 is patentably distinct from Alferness and Daniel.

Claim 10 calls for a method that comprises deploying an obstructive member comprising a valve through a lung passageway and aspirating through the deployed obstructive device. Applicants respectfully submit that new claim 10 is patentably distinct from Alferness and Daniel.

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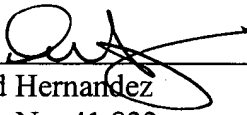
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Conclusion

Applicants respectfully submit that the pending claims are now in condition for allowance and respectfully request the same. If the Examiner has any questions regarding the foregoing, he is cordially invited to contact the undersigned so that any such matters may be promptly resolved.

Respectfully submitted,

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